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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,139	07/25/2005	Masahiko Kato	2005_1161A	4369
513                  7590                  03/08/2007 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			EXAMINER SCHELL, LAURA C	
			ART UNIT 3767	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	03/08/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

eD

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/543,139	KATO ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Laura C. Schell	3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 December 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2,3 and 5-7 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 3 and 7 is/are allowed.  
 6) Claim(s) 2 and 6 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 01 December 2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Objections***

Claims 1, 3 and 5 are objected to because of the following informalities: these claims contain reference characters in parentheses such as (VS), (VC) and (L). These reference characters should be removed from the claims in order to match the claim style of the rest of the claims, as the majority of the claim language does not use reference characters. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanaka et al. (US Patent No. 6,740,060). Tanaka discloses a dual-chamber type pre-filled syringe (Fig.7) comprising a cylindrical body which has a first end (near 15) provided with a portion for attaching an injection needle (10), a front plug member (3), a middle plug member (5) and an end plug member (4) being hermetically fitted within the cylindrical body in the mentioned order from said first end of the cylindrical body, said front plug member and said middle plug member having rear ends, respectively, on a side far away from the first end; a first chamber (6) being formed between said front

plug member and said middle plug member within said cylindrical body and accommodating a first component; a second chamber (7) being formed between said middle plug member and said end plug member within the cylindrical body and accommodating a second component; a bypass (1a) formed on an inner surface of said cylindrical body in the shape of a concave groove, said bypass being longer than said middle plug member (the length of the bypass is clearly longer than the middle plug (5)) along an axial direction of said cylindrical body and having a rear end portion (the end nearest to (12)) on a side away from the first end; wherein said first chamber communicates with said second chamber (as seen in Fig. 7) via said bypass when said middle plug member moves toward said first end to reach a position where said bypass is formed; wherein an inner volume of said cylindrical body between said first end of said cylindrical body and said rear end of said front plug member (the volume of the area between the front plug and the front end) when said rear end of said middle plug member has reached the rear end portion of the bypass (as disclosed in Fig. 7) is at least 60% of a volume of said second component (Fig. 7 clearly discloses that the volume of between the first end and the first plug member (3) is at least 60% the volume of (7), in fact it is greater than 60% the volume of (7)) and not more than said volume of said second component (upon close review, it is clear that Fig. 7 discloses that the volume between front plug member and the front end is less than the volume of (7)).

In regards to claim 6, Tanaka discloses that the length of the middle plug member (5) along an axial direction of said cylindrical body is set to a dimension which is 75-100% of an inner diameter of said cylindrical body (when measured by the

examiner, and also evident upon visual inspection of Fig. 7, the length of the middle plug member is between 75 and 100% the inner diameter of the cylindrical body).

***Allowable Subject Matter***

Claims 3 and 7 are allowed. The following is a statement of reasons for the indication of allowable subject matter: the subject matter not found or disclosed by the prior art is the dual-chamber type pre-filled syringe in which the spacing between the first end of the cylindrical body and the rear end of the first plug member is not more than 30 mm when the rear end of the middle plug member has reached the rear portion of the bypass.

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments with respect to claims 2, 3 and 5-7 have been considered but are moot in view of the new ground(s) of rejection. Upon updating the search, the Tanaka reference was found to anticipate claims 2 and 6.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LCS

*LCS*

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*